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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,736	04/16/2004	James R. Matson	067062.0129	1355

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EXAMINER

DEAK, LESLIE R

ART UNIT	PAPER NUMBER
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3761

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08/09/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/826,736	Applicant(s) MATSON ET AL.	
	Examiner Leslie R. Deak	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :5/22/07, 12/19/06, 10/26/06, 6/19/06, 5/8/06, 12/13/05, 9/15/05, 8/19/05, 5/6/05, 5/04/04.

DETAILED ACTION

1. As per a conversation with applicant's representative on 23 July 2007, the following is a supplemental non-final rejection with a corrected statement of rejected claims under 35 USC 103.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 2, and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 787 500 A1 to Wratten et al.

In the specification and figures, Wratten discloses the device as claimed by applicant. With regard to claims 1-2 and 5, Wratten discloses a hemofiltration system that is capable of treating the illness as claimed by applicant. The system comprises a hemofilter 5 that is capable of removing ultrafiltrate from a bloodstream 3, creating a filtered blood stream at 9 and an ultrafiltrate stream at 8. The system further comprises adsorptive device 11/12 that receives ultrafiltrate and is capable of removing inflammatory mediators to create an postadsorption ultrafiltrate stream. The adsorbent material may be material having activated carbon, hydrophobic or ion exchange resins, and combinations thereof (see p1 of specification, FIG 1). The device further comprises

tubing that is used to combine the postadsorption ultrafiltrate stream with the filtered blood stream in a reservoir 4 for return to the patient.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 3, 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 787 500 A1 to Wratten et al.

In the specification and figures, Wratten discloses the apparatus substantially as claimed by applicant (see rejection above) with the exception of the composition of the ultrafiltrate and the polycarbonate jacket.

With respect to claim 3, it is well known in the art that ultrafiltrate refers to filtered plasma water, solutes, and molecules such as blood peptides and proteins that are passed through the filter membrane to create the filtrate.

With respect to the limitation of claim 4 to include a polycarbonate jacket, it is well known in the art of blood filtration for a filter to comprise a housing (seen to be equivalent to applicant's "jacket") to enclose the membrane wherein the housing would be formed of a plastic or polymer. Therefore, it would also have been obvious to one having ordinary skill in the art to chose polycarbonate as the material for the housing/jacket, since it has been held to be within the general skill of a worker in the art

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to select a known material on the basis for its suitability for the intended use as a matter of obvious design choice. See MPEP 2144.07. Polycarbonate is widely used in the medical art since it is a biocompatible material and a relatively inexpensive material.

6. Claims 6-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 787 500 A1 to Wratten et al in view of US 5,846,419 to Nederlof.

In the specification and figures, Wratten discloses the apparatus substantially as claimed by applicant (see rejection above) with the exception of a "means for selectively combining" the filtered blood and postadsorption ultrafiltrate for return to the patient.

With regard to applicant's of claim 6, the language appears to be an attempt to invoke 35 USC 112, 6th paragraph interpretation of the claims. A claim limitation will be interpreted to invoke 35 U.S.C. 112, sixth paragraph, if it meets the following 3-prong analysis:

- (A) the claim limitations must use the phrase "means for " or "step for; "
- (B) the "means for " or "step for " must be modified by functional language;
and
- (C) the phrase "means for " or "step for " must not be modified by sufficient structure, material or acts for achieving the specified function.

In the instant case, applicant appears to have met the limitations set forth in MPEP § 2181, and examiner has turned to the specification for clarification.

In the specification, applicant defines the "means for selectively combining" as tubing, valves, and pumps that are operable to selectively control the combination. Accordingly, the examiner is interpreting the "means for selectively

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combining” to encompass tubing, valves, and their equivalents. Equivalent structures may include those that perform the function specified in the claim, structures that are not excluded by any specific definition provided in the specification for an equivalent, or is a structural equivalent of the corresponding element disclosed in the specification.

See MPEP 2183.

Nederlof discloses a hemofiltration system comprising a hemofilter 12, ultrafiltrate line 24 that can be diverted to secondary filter 60 by means of pumps and valves (see FIG 2). The valves and substitute pump 106 control the flow of the twice filtered dialysate through filter membrane 52 into reservoir 78 to be combined with filtered blood to return to the patient via line 85. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add “means for selectively combining” comprising tubes, valves, and pumps as disclosed by Nederlof, to the hemofiltration system disclosed by Wratten in order to control the flow of substitute fluid to the returned blood line, as taught by Nederlof.

With regard to claims 7 and 10, The adsorbent material may be material having activated carbon, hydrophobic or ion exchange resins, and combinations thereof (see p1 of specification, FIG 1).

With respect to claim 8, it is well known in the art that ultrafiltrate refers to filtered plasma water, solutes, and molecules such as blood peptides and proteins that are passed through the filter membrane to create the filtrate.

With respect to the limitation of claim 9 to include a polycarbonate jacket, it is well known in the art of blood filtration for a filter to comprise a housing (seen to be

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equivalent to applicant's "jacket") to enclose the membrane wherein the housing would be formed of a plastic or polymer. Therefore, it would also have been obvious to one having ordinary skill in the art to chose polycarbonate as the material for the housing/jacket, since it has been held to be within the general skill of a worker in the art to select a known material on the basis for its suitability for the intended use as a matter of obvious design choice. See MPEP 2144.07. Polycarbonate is widely used in the medical art since it is a biocompatible material and a relatively inexpensive material.

With regard to claim 11, Wratten and Nederlof suggest the apparatus substantially as claimed by applicant with the exception of a second pump to transfer a portion of the postadsorptive filtrate stream that is not returned to the patient to a drain. However, Nederlof discloses that various pumps and control schemes are operable to control the fluid flow through the system, and further discloses drain line 90. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to use a pump to direct unused postadsorption ultrafiltrate to drain 90 in the device suggested by Wratten and Nederlof in order to prevent fluid overload to the patient.

With regard to claims 12 and 15, the adsorbent material may be material having activated carbon, hydrophobic or ion exchange resins, and combinations thereof (see p1 of specification, FIG 1).

With respect to claim 13, it is well known in the art that ultrafiltrate refers to filtered plasma water, solutes, and molecules such as blood peptides and proteins that are passed through the filter membrane to create the filtrate.

With respect to the limitation of claim 14 to include a polycarbonate jacket, it is well known in the art of blood filtration for a filter to comprise a housing (seen to be equivalent to applicant's "jacket") to enclose the membrane wherein the housing would be formed of a plastic or polymer. Therefore, it would also have been obvious to one having ordinary skill in the art to chose polycarbonate as the material for the housing/jacket, since it has been held to be within the general skill of a worker in the art to select a known material on the basis for its suitability for the intended use as a matter of obvious design choice. See MPEP 2144.07. Polycarbonate is widely used in the medical art since it is a biocompatible material and a relatively inexpensive material.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

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F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-15 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4-8, 12-16, 24-28, 30, and 31 of U.S. Patent No. 6,730,266 to Matson et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly presented claims are a broader recitation of the already patented device, simply omitting limitations such as pore size from the already patented claims.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- a. US 5,808,181 Wamsiedler et al
 - i. Hemofiltration with purified postdilution solution

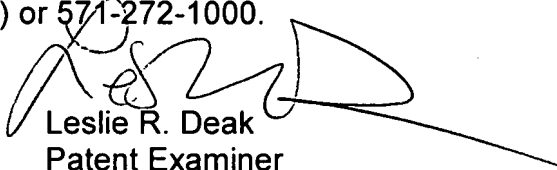
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- b. US 6,280,632 Polaschegg et al
- ii. Hemofiltration with pustdilution

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Leslie R. Deak
Patent Examiner
Art Unit 3761
23 July 2007